

REMARKS

Claims 1-3, 8 and 11-14 were pending in the application. New claims 55-60 are submitted herein and no claims are canceled. After entry of this amendment, **claims 1-3, 8, 11-14 and 55-60 will be pending.**

Claim 1 is amended to clarify that the nucleic acid molecule encodes a polypeptide fragment having at least 85% sequence identity with amino acid residues 128-224 of SEQ ID NO: 8. Support for this amendment can be found, for example, at page 5, lines 14-19 of the specification. Claim 2 is amended to remove "from about residue" for clarity. Claim 13 is amended to correct an obvious typographical error.

New claims 55-60 find support in the application as originally filed, such as, for example, at page 3, lines 23-25 and page 5, lines 14-19 of the specification.

No new matter is introduced by these amendments.

OBJECTIONS TO THE SPECIFICATION

The specification is objected to as failing to comply with the requirements of 37 C.F.R. §§1.821 to 1.825 for the disclosure of polypeptide sequences on pages 15 and 19-23 of the specification. Applicants point out that each of the amino acid sequences recited on pages 15 and 19-23 of the specification were set forth in the Sequence Listing submitted January 19, 2005. In addition, the Preliminary Amendment filed January 19, 2005 amended the specification to insert sequence identifiers for each of the amino acid sequences. Accordingly, Applicants submit the specification is in compliance with 37 C.F.R. §§1.821 to 1.825 and request withdrawal of the objection.

REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

Claims 1-3, 8 and 11-14 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Office alleges the specification does not disclose the broad genera of polynucleotide variants and fragments encompassed by the pending claims. Applicants traverse this rejection.

The pending claims

Claim 1 is directed to an isolated nucleic acid molecule which encodes a polypeptide, wherein the polypeptide is a fragment of the polypeptide sequence of SEQ ID NO: 8, having at least 85% sequence identity with residues 128-224 of the amino acid sequence of SEQ ID NO: 8, wherein the polypeptide inhibits the apoptotic activity of p53. Claim 2 specifies that the polypeptide is a fragment consisting of amino acid residues 128-224 of SEQ ID NO: 8. The remainder of the rejected claims depend from claim 1 or claim 2 and thus incorporate all limitations of these claims.

New claims 55-58 specify that the polypeptide fragment has at least 90%, 95%, 97% or 99% sequence identity with residues 128-224 of the amino acid sequence of SEQ ID NO: 8. New claim 59 is directed to an isolated nucleic acid molecule which encodes a polypeptide, wherein the amino acid sequence of the polypeptide has at least 95% sequence identity with residues 128-224 of the amino acid sequence presented in SEQ ID NO: 8. New claim 60 is directed to an isolated nucleic acid molecule which encodes a polypeptide, wherein the amino acid sequence of the polypeptide consists of residues 128-224 of the amino acid sequence presented in SEQ ID NO: 8.

Applicants were in possession of the full scope of the claims

First, Applicants submit claim 2, as amended herein, is in compliance with the written description requirement. As stated above, the nucleic acid molecule of claim 2 encodes a polypeptide *consisting of amino acid residues 128-224 of SEQ ID NO: 8*, which the Office action indicates (see page 3) is supported by the written description. Similarly, Applicants submit dependent claim 3 and new claim 60 also are in compliance with the written description requirement.

Second, Applicants submit the remainder of the claims (claims 1, 8, 11-14 and new claims 55-59), which are directed to nucleic acid molecules encoding polypeptides having at least 85% sequence identity with amino acid residues 128-224 of SEQ ID NO: 8, are fully supported by the written description. The Office alleges the specification does not provide sufficient structural features common to the claimed genus. However, the claimed nucleic acid molecules each encode polypeptides which share the common structure of having at least 85% (including at least 90%, 95%, 97% or 99%) sequence identity with amino acid residues 128-224

of SEQ ID NO: 8. Furthermore, the specification teaches that the claimed nucleic acid molecules include those encoding polypeptides with sequence variations, such as fragments or polypeptides comprising substitutions, additions, deletions and/or truncations. The specification further teaches that substitutions can include conservative substitutions, and provides specific examples of suitable amino acid replacements that result in functionally equivalent polypeptides (see, for example, page 4, line 25 to page 5, line 12 of the specification). In addition, the specification teaches that the polypeptides sequences encoded by the claimed nucleic acid molecules can have at least 75%, at least 85%, at least 90%, at least 95%, at least 97% or at least 99% sequence identity with the disclosed polypeptides (see page 5, lines 14-19 of the specification). Thus, given the teachings of the specification, it would have been clear to one of skill in the art that Applicants were in possession of the full scope of the claims at the time the application was filed.

Summary

For at least the reasons stated above, Applicants submit the pending claims fully comply with the written description requirement. Accordingly, Applicants request withdrawal of this rejection under 35 U.S.C. §112, first paragraph.

REJECTION UNDER 35 U.S.C. §102

Claims 1-3, 8 and 11-14 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Rosen *et al.* (WO 00/55175). The Office alleges Rosen *et al.* teach a nucleic acid molecule encoding a polypeptide (SEQ ID NO: 36), which is a 217 amino acid fragment of instant SEQ ID NO: 8, and which binds p53. The Office further states that Rosen *et al.* teach that the nucleic acid is isolated from humans; expression vectors comprising the nucleic acid; cells transformed or transfected with the nucleic acid; and pharmaceutical compositions comprising the nucleic acid. Applicants traverse this rejection.

The Rosen *et al.* polypeptide (SEQ ID NO: 36) is 217 amino acids in length. As shown in Exhibit A, alignment of the Rosen *et al.* polypeptide and instant SEQ ID NO: 8 demonstrates that residues 1-190 of the Rosen *et al.* polypeptide share 99% identity with a portion of SEQ ID NO: 8, specifically, residues 128-317. However, contrary to the Office's assertion, the Rosen *et al.* polypeptide is not a fragment of SEQ ID NO: 8 as residues 191-217 of the polypeptide share

no sequence similarity with SEQ ID NO: 8. In addition, as recited herein, claim 1 is directed to an isolated nucleic acid molecule which encodes a polypeptide, wherein said polypeptide is a fragment of the polypeptide sequence represented in SEQ ID NO: 8 having at least 85% sequence identity with residues 128-224 of the amino acid sequence presented in SEQ ID NO: 8. The Rosen *et al.* polypeptide is not a fragment of SEQ ID NO: 8, nor does the polypeptide have at least 85% sequence identity with residues 128-224 of SEQ ID NO: 8. Rather, the 217 amino acid Rosen *et al.* polypeptide shares approximately 45% sequence identity with residues 128-224 of instant SEQ ID NO: 8.

Thus, Rosen *et al.* does not anticipate the rejected claims, or new claims 55-59. Accordingly, Applicants request withdrawal of this rejection under 35 U.S.C. §102(b).

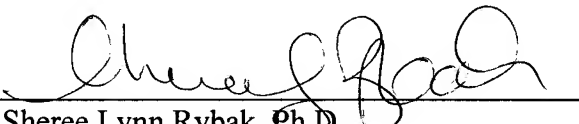
CONCLUSION

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Withdrawal of the pending rejections and allowance of the claims is respectfully requested. If the examiner believes that there are any remaining issues in the case that could be resolved by a telephonic interview, the Examiner is encouraged to contact the representative for Applicants listed below the discuss any outstanding matters.

Respectfully submitted,

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Blast 2 Sequences results

PubMed

Entrez

BLAST

OMIM

Taxonomy

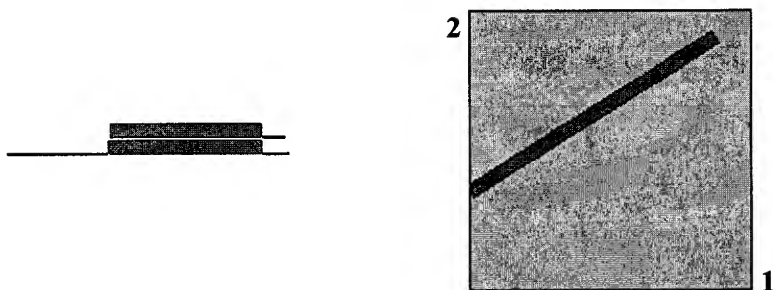
Structure

BLAST 2 SEQUENCES RESULTS VERSION BLASTP 2.2.16 [Mar-25-2007]

Matrix **BLOSUM62** gap open: **11** gap extension: **1**
x_dropoff: **0** expect: **10.0000** wordsize: **3** Filter ☒ View option **Standard**
Masking character option **X for protein, n for nucleotide** Masking color option **Black**
☐ Show CDS translation **Align**

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Length = 217 (1 .. 217)

Sequence 2: lcl|seq_2
Length = 350 (1 .. 350)

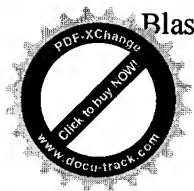


NOTE: Bitscore and expect value are calculated based on the size of the nr database.



Score = 347 bits (889), Expect = 5e-94
Identities = 189/190 (99%), Positives = 189/190 (99%), Gaps = 0/190 (0%)

Query	1	MEMRSVLRKAGSPRKARRARLNPLVLLLDAAALTGELEVQQA	60
		MEMRSVLRKAGSPRKARRARLNPLVLLLDAAALTGELEVQQA	
Sbjct	128	MEMRSVLRKAGSPRKARRARLNPLVLLLDAAALTGELEVQQA	187
Query	61	HNAICGANYSIVDFLITAGANVNSPDSHGWTPLHCAASCNXTVICMALVQHGA	120
		HNAICGANYSIVDFLITAGANVNSPDSHGWTPLHCAASCN TVICMALVQHGA	
Sbjct	188	HNAICGANYSIVDFLITAGANVNSPDSHGWTPLHCAASCNDTVICMALVQHGA	247
Query	121	SDGATAFEKCDPYREGYADCATYLADVEQSMGLMNSGAVYALWDYSAEFGDELSFREGES	180
		SDGATAFEKCDPYREGYADCATYLADVEQSMGLMNSGAVYALWDYSAEFGDELSFREGES	
Sbjct	248	SDGATAFEKCDPYREGYADCATYLADVEQSMGLMNSGAVYALWDYSAEFGDELSFREGES	307
Query	181	VTVLRRDGPE	190
		VTVLRRDGPE	
Sbjct	308	VTVLRRDGPE	317



CPU time: 0.04 user secs. 0.02 sys. secs 0.06 total secs.